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106TH CONGRESS
1ST SESSION

H. R. 3274

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to provide protection for beneficiaries of group and individual health insurance coverage, group health plans, and Medicare+Choice plans in the use of prescription drug formularies.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 9, 1999

Mr. GUTIERREZ introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and title XVIII of the Social Security Act to provide protection for beneficiaries of group and individual health insurance coverage, group health plans, and Medicare+Choice plans in the use of prescription drug formularies.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patients' Formulary Rights Act of 1999''.

SEC. 2. PATIENT PROTECTIONS AGAINST ABUSE OF FORMULARIES FOR PRESCRIPTION DRUGS.

(a) GROUP HEALTH PLANS.—

(1) PUBLIC HEALTH SERVICE ACT AMENDMENTS.—(A) Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

''SEC. 2707. STANDARDS RELATING TO USE OF FORMULARIES AND THERAPEUTIC SUBSTITUTION.

''(a) REQUIREMENTS ON USE OF FORMULARIES.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall not use a formulary unless the plan or issuer—

''(A) notifies participants, beneficiaries, and enrollees, prior to initial enrollment or coverage, and makes available at any time to health care professionals who prescribe prescription drugs under the plan or coverage of the information described in paragraph (2);

''(B) notifies participants, beneficiaries, enrollees, and health care providers who pre-

scribe covered prescription drugs under the plan or coverage on a routine and annual basis of any changes in (including deletions from) the formulary; and

''(C) in the case of a participant, beneficiary, or enrollee who is provided coverage for a prescription drug at the time the drug is removed from the formulary, to permit the participant, beneficiary, or enrollee to continue to have the drug prescribed for treatment of the same condition for which it was previously prescribed.

''(2) INFORMATION TO BE DISCLOSED.—The information described in this paragraph is as follows (with respect to prescription drug coverage under a group health plan or health insurance coverage):

''(A) EXTENT OF THERAPEUTIC SUBSTITUTION.—What constitutes the practice or therapeutic substitution that may be effected under the plan or coverage.

''(B) FORMULARY.—A complete list of all the prescription drugs included in the formulary and any changes in the formulary and how decisions to include drugs in the formulary are made.

"(C) ACCESS TO NONFORMULARY DRUGS.—The fact that a patient can have a prescription filled as written (rather than subject to therapeutic substitution) if the prescribing health care professional uses a 'dispense as written' or similar endorsement.

"(D) PAYMENT FOR NONFORMULARY DRUGS.—Whether or not the plan or coverage will cover or pay for prescription drugs not included in the formulary and, if it will, the extent of such coverage or payment.

"(E) COST-SHARING.—The copayments and other cost-sharing that is applicable under the plan or coverage for prescription drugs included on the formulary and for those not included on the formulary.

"(F) LIMITS ON PAYMENTS.—Limitations on the dollar amount the plan or coverage will cover for outpatient prescription drugs, including any such limits on a per year, per lifetime, or per diagnosis basis.

"(3) FORMULARY DEFINED.—For purposes of this subsection, the term 'formulary' includes any method under which a plan or issuer limits the particular drugs (among those that may be legally pre-

scribed for treatment) for which coverage is made available under the plan or health insurance coverage offered by the issuer.

''(b) NOTICE OF REQUIREMENT.—A group health plan under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

''(c) FORMULARY DEFINED.—For purposes of this section, the term 'formulary' includes any method under which a plan or issuer limits the particular drugs (among those that may be legally prescribed for treatment) for which coverage is made available under the plan or health insurance coverage offered by the issuer.''.

(B) Section 2723(c) of such Act (42 U.S.C. 300gg–23(c)) is amended by striking ''section 2704'' and inserting ''sections 2704 and 2707''.

(2) ERISA AMENDMENTS.—(A) Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new section:

"SEC. 714. STANDARDS RELATING TO USE OF FORMULARIES AND THERAPEUTIC SUBSTITUTION.

''(a) REQUIREMENTS ON USE OF FORMULARIES.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall not use a formulary unless the plan or issuer—

''(A) notifies participants, beneficiaries, and enrollees, prior to initial enrollment or coverage, and makes available at any time to health care professionals who prescribe prescription drugs under the plan or coverage of the information described in paragraph (2);

''(B) notifies participants, beneficiaries, enrollees, and health care providers who prescribe covered prescription drugs under the plan or coverage on a routine and annual basis of any changes in (including deletions from) the formulary; and

''(C) in the case of a participant, beneficiary, or enrollee who is provided coverage for a prescription drug at the time the drug is removed from the formulary, to permit the participant, beneficiary, or enrollee to continue to have the drug prescribed for treatment of the

same condition for which it was previously prescribed.

''(2) INFORMATION.—The information described in this paragraph is as follows (with respect to prescription drug coverage under a group health plan or health insurance coverage):

''(A) EXTENT OF THERAPEUTIC SUBSTITUTION.—What constitutes the practice or therapeutic substitution that may be effected under the plan or coverage.

''(B) FORMULARY.—A complete list of all the prescription drugs included in the formulary and any changes in the formulary and how decisions to include drugs in the formulary are made.

''(C) ACCESS TO NONFORMULARY DRUGS.—The fact that a patient can have a prescription filled as written (rather than subject to therapeutic substitution) if the prescribing health care professional uses a 'dispense as written' or similar endorsement.

''(D) PAYMENT FOR NONFORMULARY DRUGS.—Whether or not the plan or coverage will cover or pay for prescription drugs not in-

cluded in the formulary and, if it will, the extent of such coverage or payment.

''(E) COST-SHARING.—The copayments and other cost-sharing that is applicable under the plan or coverage for prescription drugs included on the formulary and for those not included on the formulary.

''(F) LIMITS ON PAYMENTS.—Limitations on the dollar amount the plan or coverage will cover for outpatient prescription drugs, including such any such limits on a per year, per lifetime, or per diagnosis basis.

''(b) NOTICE UNDER GROUP HEALTH PLAN.—The imposition of the requirement of this section shall be treated as a material modification in the terms of the plan described in section 102(a)(1), for purposes of assuring notice of such requirements under the plan; except that the summary description required to be provided under the last sentence of section 104(b)(1) with respect to such modification shall be provided by not later than 60 days after the first day of the first plan year in which such requirement apply.

''(c) FORMULARY DEFINED.—For purposes of this section, the term 'formulary' includes any method under which a plan or issuer limits the particular drugs (among

those that may be legally prescribed for treatment) for which coverage is made available under the plan or health insurance coverage offered by the issuer.''.

(B) Section 731(c) of such Act (29 U.S.C. 1191(c)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(C) Section 732(a) of such Act (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 714''.

(D) The table of contents in section 1 of such Act is amended by inserting after the item relating to section 713 the following new item:

''Sec. 714. Standards relating to use of formularies and therapeutic substitution.''.

(3) INTERNAL REVENUE CODE AMENDMENTS.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(i) in the table of sections, by inserting after the item relating to section 9812 the following new item:

''Sec. 9813. Standards relating to use of formularies and therapeutic substitution.''; and

(ii) by inserting after section 9812 the following:

"SEC. 9813. STANDARDS RELATING TO USE OF FORMULARIES AND THERAPEUTIC SUBSTITUTION.

"(a) REQUIREMENTS ON USE OF FORMULARIES.—

"(1) IN GENERAL.—A group health plan shall not use a formulary unless the plan or issuer—

"(A) notifies participants and beneficiaries, prior to initial enrollment or coverage, and makes available at any time to health care professionals who prescribe prescription drugs under the plan of the information described in paragraph (2);

"(B) notifies participants, beneficiaries, and health care providers who prescribe covered prescription drugs under the plan on a routine and annual basis of any changes in (including deletions from) the formulary; and

"(C) in the case of a participant or beneficiary who is provided coverage for a prescription drug at the time the drug is removed from the formulary, to permit the participant or beneficiary to continue to have the drug prescribed for treatment of the same condition for which it was previously prescribed.

"(2) INFORMATION.—The information described in this paragraph is as follows (with respect

to prescription drug coverage under a group health plan):

"(A) EXTENT OF THERAPEUTIC SUBSTITUTION.—What constitutes the practice or therapeutic substitution that may be effected under the plan.

"(B) FORMULARY.—A complete list of all the prescription drugs included in the formulary and any changes in the formulary and how decisions to include drugs in the formulary are made.

"(C) ACCESS TO NONFORMULARY DRUGS.—The fact that a patient can have a prescription filled as written (rather than subject to therapeutic substitution) if the prescribing health care professional uses a 'dispense as written' or similar endorsement.

"(D) PAYMENT FOR NONFORMULARY DRUGS.—Whether or not the plan will cover or pay for prescription drugs not included in the formulary and, if it will, the extent of such coverage or payment.

"(E) COST-SHARING.—The copayments and other cost-sharing that is applicable under the plan for prescription drugs included on the

formulary and for those not included on the formulary.

''(F) LIMITS ON PAYMENTS.—Limitations on the dollar amount the plan will cover for outpatient prescription drugs, including such any such limits on a per year, per lifetime, or per diagnosis basis.

''(b) FORMULARY DEFINED.—For purposes of this section, the term 'formulary' includes any method under which a plan or issuer limits the particular drugs (among those that may be legally prescribed for treatment) for which coverage is made available under the plan.''

(B) CONFORMING AMENDMENT.—Section 4980D(d)(1) of such Code is amended by striking ''section 9811'' and inserting ''sections 9811 and 9813''.

(b) INDIVIDUAL HEALTH INSURANCE.—(1) Part B of title XXVII of the Public Health Service Act is amended by inserting after section 2752 the following new section:

''SEC. 2753. STANDARD RELATING PATIENT FREEDOM OF CHOICE.

''(a) IN GENERAL.—The provisions of section 2707(a) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in

the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

''(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.''.

(2) Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)) is amended by striking ''section 2751'' and inserting ''sections 2751 and 2753''.

(c) MEDICARE+CHOICE PLANS.—Section 1852 of the Social Security Act (42 U.S.C. 1395w–22) is amended by adding at the end the following new subsection:

''(l) FORMULARY REQUIREMENTS.—

''(1) IN GENERAL.—A Medicare+Choice organization shall comply with the requirements of section 2707 of the Public Health Service Act with respect to a Medicare+Choice plan it offers in the same manner as such requirements apply to health insurance coverage offered in connection with a group health plan.

''(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as superseding other requirements of this part, except to the extent the Secretary specifically finds that such other requirements are less stringent, and do not duplicate, the requirements referred to in such paragraph.''.

(d) EFFECTIVE DATES.—

(1) GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE COVERAGE.—Subject to paragraph (4), the amendments made by subsection (a) apply with respect to group health plans for plan years beginning on or after January 1, 2001.

(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The amendments made by subsection (b) apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after such date.

(3) MEDICARE+CHOICE PLANS.—The amendments made by subsection (b) apply with respect to Medicare+Choice plans offered on or after such date.

(4) COLLECTIVE BARGAINING EXCEPTION.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more em-

ployers ratified before the date of enactment of this Act, the amendments made subsection (a) shall not apply to plan years beginning before the later of—

(A) the date on which the last collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of enactment of this Act), or

(B) January 1, 2001.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by subsection (a) shall not be treated as a termination of such collective bargaining agreement.

(e) COORDINATION OF ADMINISTRATION.—The Secretary of Labor, the Secretary of the Treasury, and the Secretary of Health and Human Services shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under the provisions of this Act (and the

amendments made thereby) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

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